AUG - 1 2001

K01 2090

510(k)
Summary of Safety and Effectiveness

Submitter: Cordis Corporation, a Johnson & Johnson Company
40 Technology Drive
Warren, New Jersey 07059

Telephone: (908) 755-8300
Fax: (908) 412-3915

Contact Person: Chuck Ryan, RAC
Manager, Regulatory Affairs
Cordis Corporation, a Johnson & Johnson Company
40 Technology Drive
Warren, New Jersey 07059

Telephone: (908) 412-7446
Fax: (908) 412-3915

Date Prepared: July 3, 2001

Trade Name: Cordis **PALMAZ® GENESIS™** Transhepatic Biliary Stent

Common Name: Biliary Stent and Accessories

Classification Name: Biliary Catheter and Accessories (per 21 CFR 876.5010)

Device Classification: Class II

Summary of Substantial Equivalence:
The design, material, components, accessories, method of delivery, fundamental technology and intended use featured with the Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent are substantially equivalent to those featured with the predecessor Cordis BX Transhepatic Biliary Stent and Delivery System (see 510(k) #K001258). In short, the subject Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent represents an unmounted (provided separately from its delivery catheter) line extension to this predecessor device.

Device Description:
The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent is a balloon-expandable, stainless steel stent that is provided unmounted (without its recommended balloon catheter delivery device). The Cordis **OPTA®** PRO Balloon Catheter is recommended for the delivery of the Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent.

The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent is hand crimped upon its recommended balloon catheter delivery device. The stent / balloon catheter assembly is then advanced over a guidewire through a sheath lumen, via the use of a metal introducer tube accessory, which is also provided separately, to an obstruction site in the biliary tree where the balloon is then inflated to expand the stent. After full expansion of the stent, the balloon is then deflated and removed.

The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent is provided sterile (via gamma irradiation) and is intended for single use only.

Intended Use:
The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent is intended for use in the palliation of malignant neoplasms in the biliary tree.

Technological Characteristics:
The Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent incorporates a design, size range, method of deployment, device and packaging materials, fundamental technology, delivery devices, intended use, and manufacturing and sterilization processes substantially equivalent to those featured with the predicate Cordis BX Transhepatic Biliary Stent and Delivery System (see 510(k) #K001258) and Cordis **PALMAZ CORINTHIAN** Transhepatic Biliary Stents (see 510(k) #K991028). The **PALMAZ GENESIS** Transhepatic Biliary Stent is provided in nominal unexpanded lengths of 29-79 mm and is designed for expanded diameters of 5-10 mm.

Performance Data:
The safety and effectiveness of the Cordis **PALMAZ GENESIS** Transhepatic Biliary Stent have been demonstrated via data collected from non-clinical design verification tests and analyses.

A statement of substantial equivalence to another product is required by 21 CFR 807.87 and relates only to whether the present product can be marketed without prior reclassification or clinical approval. The present submission is therefore not related to the coverage of any patent and is not to be interpreted as an admission or used as evidence in a patent infringement lawsuit. As the commissioner of the stated, "A determination of substantial equivalence under the Federal Food, Drug and Cosmetic Act related to the fact that the product can be lawfully marketed without pre-market approval or reclassification. This determination is not intended to have any bearing whatsoever on the resolution of patent infringement suits." 42 Federal Register 42, 50 et seq. (1977).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2001

Mr. Chuck Ryan, RAC
Manager, Regulatory Affairs
Cordis Corporation
7 Powder Horn Drive
WARREN NJ 07059

Re: K012090
Cordis PALMAZ® GENESIS™ Transhepatic
Biliary Stent (29-79 mm Lengths)
Regulatory Class: II
21 CFR 876.5010
Product Code: 78 FGE
Dated: July 3, 2001
Received: July 5, 2001

Dear Mr. Ryan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Bernard E. Statland, M.D., Ph.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012090

Device Name: Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent (29-79 mm Lengths)

FDA's Statement of the Indications For Use for device:

The Cordis PALMAZ® GENESIS™ Transhepatic Biliary Stent is indicated for the palliation of malignant neoplasms in the biliary tree.

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

David A. Seguson

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012090